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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,768	02/28/2002	Hans-Henrik Ipsen	478.1.012 DIV	2423

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WATOV & KIPNES, P.C.
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,768

Applicant(s)

IPSEN ET AL.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 38-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 38, 43, 51, 57, 63, 69, 75, 78-80, drawn to a method of detecting an antibody in a liquid sample, classified in class 435, subclass 4.
 - II. Claims 39, 41, 44, 46, 52, 58, 64, 70, 76, drawn to another method of detecting an antibody in a liquid sample, classified in class 435, subclass 7.1.
 - III. Claims 40, 42, 45, 47, 53, 59, 65, 71, 77, drawn to another method of detecting an antibody in a liquid sample, classified in class 435, subclass 7.9.
 - IV. Claims 48, 54, 60, 66, 72, drawn to a method of evaluating the effect of a specific allergy vaccination treatment, classified in class 435, subclass 7.92.
 - V. Claims 49, 55, 61, 67, 73, drawn to another method of evaluating the effect of a specific allergy vaccination treatment, classified in class 436, subclass 518.
 - VI. Claims 50, 56, 62, 68, 74, drawn to another method of evaluating the effect of a specific allergy vaccination treatment, classified in class 436, subclass 164.
 - VII. Claims 81 and 95, drawn to a method of evaluating the immunological status of a subject, classified in class 436, subclass 536.
 - VIII. Claims 82-87, 94, 96, drawn to another method of evaluating the immunological status of a subject, classified in class 436, subclass 538.
 - IX. Claims 88, 90, 92, 97, drawn to a method of evaluating the effect of allergy treatment, classified in class 436, subclass 543.

Art Unit: 1641

- X. Claims 89, 91, 93, 98, drawn to another method of evaluating the effect of allergy treatment, classified in class 436, subclass 811.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are all methods with different functions and/or steps. Specifically, the methods of Groups I-III serve the function of detecting an antibody in a liquid sample, while the methods of Groups IV-VI and IX-X are drawn to evaluating the effect an allergy treatment, and Groups VII and VIII drawn to evaluating the immunological status of a subject. In addition, the groups drawn to detecting an antibody in a liquid sample differ from each other. Specifically, the addition of a chemiluminescent compound bound to avidin or streptavidin of Groups II and III are not required of Group I, and the paramagnetic particle and magnetic separation of Group III is not required of Group II. Groups IV-VI and IX-X drawn to evaluating the effect of an allergy treatment differ from one another also. Specifically, the addition of a chemiluminescent compound bound to avidin or streptavidin of Groups V and VI are not required of Group IV, and the paramagnetic particle and magnetic separation of Group VI is not required of Group V. In addition, the use of an antibody directed against the Fc region of sample antibody of Groups IX and X are not required of any of Groups IV-VI, and Groups IX and X differ from one another in that they use different assay protocols to determine antibody content. Finally, the groups drawn to determining the immunological status of a subject (Groups VII and VIII) differ from one another. The method of Group VII uses an antibody directed against the Fab region of sample

Art Unit: 1641

antibody, while the method of Group VIII uses antibody directed against the Fc region of sample antibody.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and the search required for one group is not required of the others, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Allen Kipnes on 8/4/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

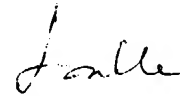
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/07/04